AUG 2 3 2011

6. 510(k) Summary

Assigned 510(k) number: K111507

Submitted by:

Centers for Disease Control and Prevention
1600 Clifton Road NE
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Date prepared: August 19, 2011

Device Name: CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel

Common or Usual Name: CDC Flu rRT-PCR Dx Panel

Regulatory Information:

Regulation Section: Reagents for detection of specific novel influenza A viruses (21 CFR 866.3332)
Classification: Class II
Product Codes: OQW, NXD, OEP, NSU
Panel: Microbiology

Predicate Devices:
- CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (K080570)
- CDC Influenza 2009 A (H1N1)pdm Real-time RT-PCR Panel (K101564)

Device Description

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is used in real-time RT-PCR assays (rRT-PCR) on the ABI 7500 Fast Dx Real-Time PCR Instrument.

The CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis (TaqMan®) probes to be used in rRT-PCR for the in vitro qualitative detection and characterization of human influenza viruses from viral RNA in respiratory specimens from patients presenting with influenza-like illness (ILI). Detection of viral RNA not only aids in the diagnosis of illness caused by seasonal and novel influenza viruses in patients with ILI, but also provides epidemiological information on influenza and aids in the presumptive laboratory identification of specific novel influenza A viruses.

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is based on technology which is used in many molecular diagnostic assays. rRT-PCR assays are one-tube assays that first reverse-transcribe specific regions of RNA into cDNA copies. The cDNA then serves as a template for a polymerase chain reaction that utilizes a thermocyclic heating and cooling of the reaction to logarithmically amplify a specific region of DNA. The probe anneals to a specific internal target sequence located between the target loci of the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades any probe molecules hybridized to amplified target sequence, causing the reporter dye to separate from the quencher dye, and generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle. Amplification of targets is reflected by logarithmic increase in fluorescence over time in comparison to background signal.

Intended Use

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is intended for use in real-time RT-PCR (rRT-PCR) assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information:

- For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture.
- For determination of the subtype of seasonal human influenza A virus as seasonal A/H1, A/H3, and/or A/H1pdm09 from viral RNA in upper respiratory tract clinical

specimens (including NPS, NS, TS, NA, NW and NPS/TS) and lower respiratory tract specimens (including BAL, BW, TA, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture.

- For the presumptive identification of virus in patients who may be infected with influenza A subtype A/H5 (Asian Lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical and epidemiological risk factors.
- To provide epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when influenza viruses A/H1 and A/H3 were the predominant influenza A viruses in circulation and during a season when the A/H1pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.

Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A/H5 specimens. The definitive identification of influenza A/H5 (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

Substantial Equivalence Comparison

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel merges two previously FDA-cleared CDC devices and is equivalent to the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (K080570) and the CDC Influenza 2009 A (H1N1)pdm Real-time RT-PCR Panel (K101564). These devices were developed to the same specifications and utilize the same real-time RT-PCR technology to detect influenza A and influenza B in human respiratory specimens. The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel further detects and differentiates influenza A and B viruses and characterizes influenza A viruses as A/H1, A/H3 subtypes, A/H1pdm09, and A/H5 using real-time RT-PCR. All three devices utilize the same instrumentation, the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument, which has been granted marketing clearance by FDA (K082562). The CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (K080570) and the CDC Influenza 2009 A (H1N1)pdm Real-time RT-PCR Panel (K101564) were granted marketing clearance by the FDA on September 30, 2008, and June 22, 2010, respectively.

	CDC Human Influenza Virus Real-time PCR Diagnostic Panel	**CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (K080570)**	**CDC Influenza 2009 A (H1N1)pdm Real-time RT-PCR Panel (K101564)**
Intended Use	The CDC Human Influenza Virus Real-Time PCR Diagnostic Panel is intended for use in Real-time RT-PCR assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information: 1) for qualitative detection of influenza virus type A or B from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs), and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture, 2) for determination of the subtype of seasonal human influenza A virus as seasonal A/H1, A/H3, and/or A/H1pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs nasal	The Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel is intended for use in Real-time RT-PCR assays on an ABI 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information: for qualitative detection of influenza virus type A or B in symptomatic patients from viral RNA in nasopharyngeal and/or nasal swab specimens, for determination of the subtype of seasonal human influenza A virus, as seasonal A/HI or A/H3, if present, from viral RNA in nasopharyngeal and/or nasal swab specimens, for presumptive identification of virus in patients who may be infected with influenza A subtype A/H5 (Asian lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical and epidemiological risk	The CDC rRT-PCR A(H1N1)pdm09 Flu Panel is intended for use in real-time RT-PCR assays on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument for the *in vitro* qualitative detection of influenza virus type A and 2009 A/H1N1 viral RNA from nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, dual nasopharyngeal / throat swabs and lower respiratory tract specimens from human patients with signs and symptoms of respiratory infection and/or from viral culture, in conjunction with clinical and epidemiological risk factors.

	aspirates, nasal washes and dual nasopharyngeal/throat swabs), and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture, 3) for the presumptive identification of virus in patients who may be infected with influenza A subtype A/H5 (Asian Lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical and epidemiological risk factors, and 4) to provide epidemiologic information for surveillance of the circulating influenza viruses.	factors to provide epidemiologic information for surveillance for influenza viruses.	
Specimen Types	Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs, bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue and virus culture	Nasopharyngeal swabs, nasal swabs, and virus culture	Nasopharyngeal swabs, nasal swabs, nasal aspirates, nasal washes, dual collected nasopharyngeal and throat swabs, bronchoalveolar lavages, bronchial washes, and tracheal aspirates, and virus culture.
Technology	Real-time RT-PCR	Real-time RT-PCR	Real-time RT-PCR
Required Instrumentation	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument	Applied Biosystems 7500 Fast Dx Real- Time PCR Instrument	Applied Biosystems 7500 Fast Dx Real- Time PCR Instrument
Organism Detected	Universal influenza A viruses, Swine-origin influenza A viruses, Influenza B viruses, and Influenza A subtypes: seasonal A/H1, A/H3, A/H1pdm09 , and A/H5 (Asian Lineage)	Universal influenza A virus, subtypes A/H1 and A/H3; Influenza B virus; Influenza A virus, subtype A/H5 (Asian lineage)	Universal influenza A, Swine-Origin Influenza A, and A/H1pdm09 subtype
Nucleic Acid Extraction	Yes	Yes	Yes
Extraction Method	• QIAamp® DSP Viral RNA Mini Kit, Qiagen Inc. • MagNA Pure Compact -Total Nucleic Acid Kit, Roche Applied Science • MagNA Pure Compact – RNA Isolation Kit, Roche Applied Science • MagNA Pure LC - RNA Isolation Kit II, Roche Applied Science • Qiagen QIAcube with QIAamp® DSP Viral RNA Mini Kit, Qiagen Inc. • NucliSENS® easyMAG®, bioMerieux	• QIAamp® Viral RNA Mini Kit, Qiagen Inc. • RNeasy® Mini Kit, Qiagen, Inc. • MagNA Pure LC RNA Isolation Kit II, Roche Applied Science • MagNA Pure Total Nucleic Acid Kit, Roche Applied Science	• QIAamp® Viral RNA Mini Kit, Qiagen Inc. • MagNA Pure Compact - Total Nucleic Acid Kit, Roche Applied Science • MagNA Pure Compact – RNA Isolation Kit, Roche Applied Science • MagNA Pure LC - RNA Isolation Kit II, Roche Applied Science • Qiagen QIAcube with QIAamp® Viral RNA Mini Kit, Qiagen Inc. • NucliSENS® easyMAG®, bioMerieux
Enzyme Master Mix	Invitrogen SuperScript™ III Platinum® One-Step	Invitrogen SuperScript™ III Platinum® One-Step	Invitrogen SuperScript™ III Platinum® One-Step

	Quantitative RT-PCR Kits (with or without ROX)	Quantitative RT-PCR Kits (with or without ROX)	Quantitative RT-PCR Kits (with or without ROX)

Performance Characteristics

For analytical and clinical performance characteristics, please refer to previously FDA-cleared CDC 510(k) Premarket Notifications:

1. K080570 – Cleared on September 30, 2008: CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel
2. K101564 – Cleared on June 22, 2010: CDC Influenza 2009 A (H1N1)pdm Real-Time RT-PCR Panel

Additional performance data were collected during the 2010-2011 influenza season. Recent circulating seasonal influenza virus strains can be detected by the CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel and the CDC Influenza 2009 A (H1N1)pdm Real-Time RT-PCR Panel as demonstrated by analytical testing of the 49 original specimens received from US public health laboratories that contained 24 Influenza A/H3 (49%) and 25 Influenza B (51%).

Eighteen original lower respiratory specimens were received from US public health laboratories during the 2010-2011 influenza season from hospitalized patients or fatal cases. The CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel and the CDC Influenza 2009 A (H1N1)pdm Real-Time RT-PCR Panel detected influenza A/H3, A/H1pdm09, and influenza B in bronchoalveolar lavage, bronchial washes, tracheal aspirates, sputum, and lung tissue specimens, verifying detection of recent circulating influenza viruses in the lower respiratory tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Silver Spring, MD 20993

National Center for Emerging and Zoonotic Infectious Diseases
Center for Disease Control and Prevention
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Associate Director for Regulatory Affairs
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1600 Clifton Road, N.E. MS-C12
Atlanta, GA 30333

AUG 23 2011

Re: K111507

Trade/Device Name:	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel
Regulation Number:	21CFR §866.3332
Regulation Name:	Reagents for detection of specific novel influenza A viruses.
Regulatory Class:	Class II
Product Code:	OQW, NXD, OEP, NSU
Dated:	May 31, 2011
Received:	June 1, 2011

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111507

Device Name: **CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel**

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Performance characteristics for influenza were established during a season when influenza viruses A/H1 and A/H3 were the predominant influenza A viruses in circulation and during a season when the A/H1pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.

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Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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Prescription Use __x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

Tamara Feldblyum
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K111507